

~~2~~ ~~32~~. A sustained-release formulation for oral administration containing a cGMP PDE-5 inhibitor, which comprises a core containing the cGMP PDE-5 inhibitor and an outer coating impermeable to the cGMP PDE-5 inhibitor, the outer coating having an aperture for release of the cGMP PDE-5 inhibitor, provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

~~3~~ ~~33~~. A controlled-release formulation for oral administration containing sildenafil, or a pharmaceutically acceptable salt thereof, provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

~~4~~ ~~34~~. A formulation as claimed in claim ~~33~~ ³, wherein the cGMP PDE-5 inhibitor is sildenafil citrate.

~~5~~ ~~35~~. A sustained-release formulation for oral administration containing hydroxypropylmethyl cellulose and containing a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion; provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

~~6~~ ~~36~~. A sustained-release formulation for oral administration containing a buffering agent and a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion, provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

7/37. A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose has a number average molecular weight in the range 80,000-250,000.

8/38. A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose has a degree of methyl substitution in the range 19-30%.

9/39. A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose has a degree of hydroxy substitution in the range 7-12%.

10/40. A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose makes up 10-50% by weight of the formulation.

11/41. A formulation as claimed in claim 31, wherein a multiplicity of coated cores is present.

12/42. A formulation as claimed in claim 41, wherein the core also includes a buffering agent.

13/43. A formulation as claimed in claim 31, wherein the release rate-controlling membrane comprises an ammonio-methacrylate copolymer and a plasticizer.

44. A controlled-release formulation for oral administration containing 5-50% by weight of the formulation of a cGMP PDE-5 inhibitor; provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers; said formulation.

45. A controlled-release formulation for oral administration containing a cGMP PDE-5 inhibitor; provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers, said formulation characterized in that the rate at which the cGMP PDE-5 inhibitor is released therefrom is substantially independent of the pH of the surroundings.

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D3 46. A process for the production of a sustained-release formulation comprising a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion, which includes the steps of:

- (a) mixing the cGMP PDE-5 inhibitor with a matrix material, and pressing into tablets;
- (b) forming a core comprising the cGMP PDE-5 inhibitor and then coating the core with a release rate-controlling membrane; or
- (c) forming a core containing the cGMP PDE-5 inhibitor and then coating the core with a coating impermeable to the cGMP PDE-5 inhibitor; respectively.

47. A method of treating or preventing sexual dysfunction, which comprises administering a controlled-release formulation comprising a cGMP PDE-5 inhibitor to a mammal in need of such treatment or prevention.

16 48. The method of claim *15* 47, characterized in that, following administration, the mammal's sexual function is substantially improved for or after a sustained period of time.

Sub
D3 49. A method of improving sexual function in a mammal, which comprises administering a controlled-release formulation comprising a cGMP PDE-5 inhibitor to the mammal.

18 50. The method of claim *17* 49, characterized in that, following administration, the mammal's sexual function is substantially improved for or after a sustained period of time.